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Effect of Back Supports on Back Strength in Patients With Osteoporosis: A Pilot Study

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• *Objective*: To determine the effect of application of back supports on back strength in subjects with osteoporosis.

• *Design*: In a prospective, randomized, controlled study, we compared compliance and evaluated changes in back strength in 45 women with osteoporosis who were older than 40 years of age and were randomly assigned to one of three groups: (1) postural exercise only, (2) postural exercise and a conventional thoracolumbar support, or (3) postural exercise and a Posture Training Support (PTS) (a weighted kypho-orthosis).

• *Material and Methods*: Of the 45 study participants, 15 were assigned to a PTS group, 15 to conventional thoracolumbar support, and 15 to no orthosis. All subjects were instructed in basic body mechanics and postural exercises. Back extensor strength, grip strength, and patient's physical activity were measured at baseline and at subsequent 8-week intervals for a 16-week period. Each patient's compliance during the study period was also recorded.

• *Results*: Compliance was poor among the thoracolumbar group; only 5 of the 15 subjects completed the study ($P<0.001$), in comparison with 11 of the 15 patients in the control group and all 15 in the PTS group. Analysis revealed statistically significant mean increases in back strength in the PTS group (23%) and the control group (13%) and a nonsignificant increase in the thoracolumbar group (15%), although poor compliance in the thoracolumbar group yielded insufficient power to detect a significant difference in this group. No statistically significant difference was found between the improvements in the PTS and control groups, possibly because of the small sample size in this pilot study. One patient who wore the PTS for only 4 hours a day rather than 8 hours had the largest percentage increase in back extensor strength of this group (78%). At 16 weeks, decreases in back strength of more than 5% below the initial measurements were noted in 1 of 11 subjects (9%) who completed the control arm of the study, 2 of 14 (14%) who completed the PTS arm, and 2 of 5 (40%) who completed the thoracolumbar arm.

• *Conclusion*: Compliance with use of the PTS was better than that with the thoracolumbar support. Back extensor strength may increase in patients who comply with the PTS and postural exercise program. We caution, however, that this pilot study requires replication in a larger series to determine the clinical and statistical generalizability of these findings to a wider population.

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PTS = Posture Training Support

BACKGROUND

Osteoporosis is the most common metabolic bone disease in the United States. The most disfiguring effect of osteoporosis is on the spine because trabecular bone is metabolically the most affected bone tissue at the postmenopausal stage. Because of the multifactorial nature of back pain and the subjective nature of this disorder, available data on either the objective or the subjective efficacy of various treatment modalities are scarce.[1] Nonetheless, bracing of the spine has long been widely practiced. According to Perry,[2] only 14 of 3,410 American orthopedic surgeons surveyed in 1970 had never prescribed some type of support for back problems. Therefore, determining the extent of compliance and the effectiveness of treatment with use of back orthoses seems appropriate.

The use of back supports to minimize or prevent complications of osteoporosis is widespread, yet the few related

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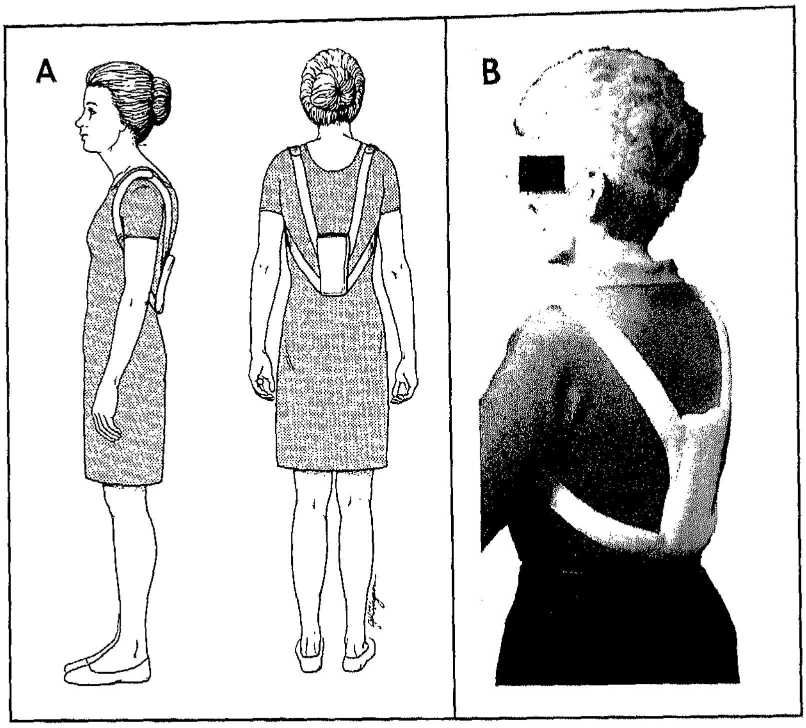

Fig. 1. *A* and *B*, Posture Training Support (PTS). This orthosis is believed to operate on the principle of providing weight below the scapulae to act as a proprioceptive reinforcer and to improve posture. (*A* from PTS: Posture Training Support. Jackson [MI]: Camp International, 1990. *B* from PTS Posturing brochure A838. Jackson [MI]: Camp International, 1991. By permission of Bissell Healthcare Corporation.)

published studies reveal considerable limitations of currently available rigid or soft thoracolumbar and lumbosacral supports, including the following: (1) poor compliance because of discomfort or limitation of motion, (2) expense, (3) unappealing appearance, and (4) medical contraindications to the use of rigid supports.[3] Thus, a need exists not only for development of new supports for patients with osteoporosis but also for ergonomic validation of their use in actual practice.

Many studies done to analyze the function of back orthoses have concentrated on their theoretical mechanics while being worn by a patient rather than on their effects on the patient (that is, their effects on back extensor strength, pain, and posture in an actual clinical situation). For example, the studies by Bartelink[4] and Million and associates[1] describe the effects of various orthoses on abdominal pressure and lumbar intervertebral disk pressure but do not address difficulties with cost, compliance, and aesthetics, which often limit long-term clinical intervention in an actual patient encounter. Demonstration of efficacy is insufficient; Ahlgren and Hansen[5] showed that only three-quarters of the patients wore an orthosis immediately after it had been prescribed. Thus, as part of the initial trials of the efficacy of a back orthosis, studying patients' impressions and actual use of such a device is important.

The current study was thus conceived to evaluate patient compliance and impressions of the Posture Training Support (PTS) (a weighted kypho-orthosis) (Fig. 1). Preliminary experience with the PTS[6] has indicated that the unobtrusive aesthetics of this device improve patient acceptance in comparison with more conventional spinal orthoses.

PATIENTS AND METHODS

Study Subjects.—After recruitment of sequential patients whose Mayo Clinic records indicated a previous diagnosis of osteopenia or osteoporosis, 45 women older than 40 years of age (range, 43 to 87) were enrolled in the study. For inclusion in the study, patients had to fulfill the following criteria: (1) have confirmation of osteoporosis or osteopenia through either bone mineral density evaluation (density below fracture threshold) or radiologic diagnosis of osteopenia on plain thoracolumbar roentgenograms, (2) be 40 years old or older, and (3) be female. If anteroposterior and lateral thoracolumbar roentgenograms of the spine had not been obtained in the previous 12 months, they were obtained to confirm the diagnosis and establish a baseline.

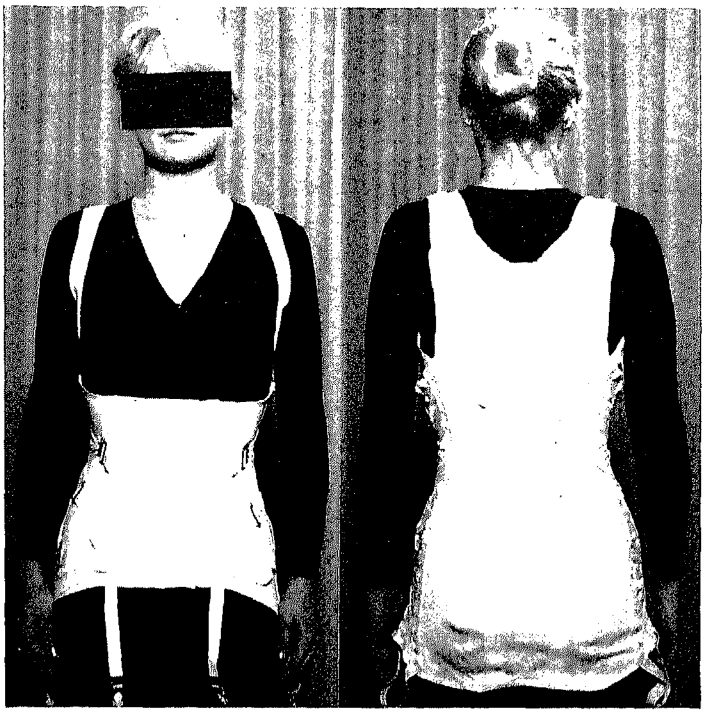

Fig. 2. Conventional thoracolumbar support. (From Sinaki M. Exercise and physical therapy. In: Riggs BL, Melton LJ III, editors. Osteoporosis: Etiology, Diagnosis, and Management. New York: Raven Press, 1988: 457-479. Copyright Mayo Foundation.)

Patients were excluded from this study if they (1) had previously undergone a spinal operation, (2) had a known bony or metastatic neoplasm, (3) had had medical treatment that affected muscle strength within the past year (such as corticosteroids), (4) had medical problems that could affect compliance, (5) had a contraindication to participation in back strength measurement or application of a conventional thoracolumbar back support (such as chronic obstructive pulmonary disease, acute compression fracture, pain limiting maximal effort during measurement of back extensor strength, weight more than 30% above ideal, orthopnea, or diaphragmatic hernia), (6) had chronic nonback pain, or (7) were participating in any back exercise or back support program or back strengthening program or had participated in such a program during the 6 months preceding the study.

In addition to the 45 patients who were enrolled in the study, 53 patients interviewed for the study were found to be ineligible. The reasons for ineligibility (some patients had more than one reason) included diaphragmatic hernia (15 patients), no clear diagnosis of osteoporosis (11), current participation in back extensor strengthening program (7), obesity (4), past spinal operation (3), concurrent participation in another intervention study of osteoporosis (3), acute compression fracture (2), current use of a thoracolumbar support (2), current use of corticosteroids (2), current use of a PTS (1), current use of a Mikros support (1), unwillingness to participate for duration of study (1), chronic obstructive pulmonary disease (1), and contraindication to measurement of back extensor strength (1 wheelchair ambulator with a history of cerebrovascular accident, 1 patient with decreased shoulder motion attributable to a clavicular fracture, and 1 patient with substantial discomfort, due to idiopathic chronic abdominal pain, while lying prone).

Study Design.—Baseline back extensor strength was assessed with the BID-2000 dynamometer,[7] baseline grip strength was assessed with a handheld dynamometer, and subjects were asked to complete a questionnaire about baseline physical activity (based on a previously published physical activity scale[8]). Before randomization, all subjects were instructed in basic body mechanics and postural exercises (deep breathing and seated back extension) because these exercises are customarily prescribed with the PTS and thus might have been a confounding variable if not applied to all subjects. Subjects were then randomly assigned for 16 weeks to one of the following groups: no orthosis, conventional thoracolumbar support (Fig. 2), or the PTS (Fig. 1). Randomization was accomplished by having each patient select 1 of 45 preprinted assignment forms; each contained a

Table 1.—**Raw Scores for Back Extensor Strength, Grip Strength, and Physical Activity Scale in 15 Patients With Osteopenia or Osteoporosis Who Wore a Thoracolumbar Support and Exercised***

	BES (lb)			Grip (R) (lb)			PAS†		
Case	Baseline	8 wk	16 wk	Baseline	8 wk	16 wk	Baseline	8 wk	16 wk
31	36	56	54	55	58	60	7	7	9
32	46	49	42	50	46	48	7	7	7
33	41	35	49	35	40	47	2	2	2
34	35	46	44	45	52	50	5	5	5
35	37	40	35	47	45	46	5	5	5
Mean	39	45	45						
Excluded patients‡									
36	33	...	...	35	...	...	9	...	...
37	37	...	...	62	...	...	5	...	...
38	30	...	...	55	...	...	5	...	...
39	36	...	...	58	...	...	5	...	...
40	50	...	...	70	...	...	7	...	...
41	58	...	...	60	...	...	13	...	...
42	44	...	...	48	...	...	7	...	...
43	34	31	...	55	50	...	5	5	...
44	Withdrew immediately after randomization§								
45	Withdrew immediately after randomization§								

*BES = back extensor strength; PAS = physical activity scale; R = right hand.
†Range of score is 0-18.
‡Excluded patients underwent assessment by a physician to ensure proper fit of support. Because of discomfort from support, cases 36-42 withdrew from study before 8 weeks, and case 43 withdrew after 8 weeks.
§Because of preference for Posture Training Support despite initial consent to randomization.

sealed envelope. The remaining collection of assignment envelopes was reshuffled after each patient assignment. After each 8-week period, back extensor strength and grip strength were reevaluated, and patients completed a questionnaire about compliance with the study and level of physical activity.

All measurements of back extensor strength were determined by a physical therapy assistant blinded to the patients' study group assignment. All patients in the thoracolumbar and PTS groups were telephoned periodically (approximately every 2 weeks) by a physician, who monitored progress and encouraged compliance with use of the back support.

Each subject randomized to use a back orthosis was instructed in its conventional usage (PTS, 4 hours twice daily; conventional support, continuously while up and about). All subjects were requested to complete a diary in which they recorded their physical activity, and subjects in the PTS and thoracolumbar groups were asked about compliance with the orthosis schedule.

RESULTS

The randomized groups showed no statistical difference in mean age (or range) (PTS, 64.2 years [48 to 84]; control, 70.1 years [51 to 84]; and thoracolumbar support, 68.1 years [57 to 87]) or lumbar bone mineral density (PTS, 0.72 g/cm^2 [N = 12]; control, 0.72 g/cm^2 [N = 10]; and thoracolumbar support, 0.71 g/cm^2 [N = 8]). No significant difference (Kruskal-Wallis statistic) was found among the three randomized groups of 15 subjects in regard to baseline back extensor strength (P = 0.20), grip strength (P = 0.52), or physical activity (P = 0.12).

Compliance was worse (P<0.001, χ^2 contingency table) among the thoracolumbar group (Table 1) than in either the control group (Table 2) or the PTS group (Table 3); only 5 of the 15 patients in the thoracolumbar group completed the study, but 11 of the 15 patients in the control group and all 15 in the PTS group completed the study. All patients who completed the study reported using assigned orthoses (where applicable) and completing home exercises for more than 80% of the assigned hours or sessions. All patients with compliance below this level elected to withdraw from the study.

During the 16-week study, statistically significant increases in back extensor strength were noted in the PTS group (23%; P<0.02, Wilcoxon signed rank test) and in the control group (13%; P<0.054); a nonsignificant increase

Table 2.—**Raw Scores for Back Extensor Strength, Grip Strength, and Physical Activity Scale in 15 Patients With Osteopenia or Osteoporosis Enrolled in Control Group (Postural Exercises, No Orthosis)***

	BES (lb)			Grip (R) (lb)			PAS†		
Case	Baseline	8 wk	16 wk	Baseline	8 wk	16 wk	Baseline	8 wk	16 wk
1	34	36	36	40	41	39	5	5	5
2	73	80	81	75	70	72	5	5	4
3	50	50	48	60	58	60	5	5	5
4	32	50	32	70	70	72	5	5	4
5	20	19	22	40	40	45	4	4	4
6	39	68	61	60	59	60	6	6	6
7	69	65	72	65	70	67	7	7	7
8	21	29	24	55	55	50	5	6	6
9	52	49	49	35	35	32	2	2	2
10	40	42	40	50	47	50	5	5	5
11	68	90	95	58	50	43	7	7	5
Mean	45	53	51						
Excluded patients									
12‡	16	...	...	40	...	...	2	...	...
13‡	27	18	...	55	57	...	2	2	...
14§	34	...	...	62	...	...	2	...	...
15	Withdrew immediately after randomization∥								

*BES = back extensor strength; PAS = physical activity scale; R = right hand.
†Range of score is 0-18.
‡Withdrew because of acute compression fracture.
§Withdrew to try more active intervention.
∥Decided to try more active intervention despite initial consent to randomization.

in back strength was noted in the thoracolumbar group (15%; $P>0.062$), although the small group of subjects who completed this arm of the study reduced the power to detect a difference to 1 standard deviation to less than 0.6. No statistically significant difference was found between the improvements in the PTS and control groups ($P>0.25$, Kruskal-Wallis statistic); even if a parametric distribution of data is assumed, our subset of 11 patients who completed the control portion of the study yielded an approximate power of only 0.6 to detect a difference in strength of 1 standard deviation with a significance of $P = 0.05$. No significant change ($P>0.05$, Wilcoxon signed rank test) was detected in grip strength or physical activity during the study in any of the three groups; thus, the likelihood of routine physical activities acting as confounding variables was minimized.

One patient in the PTS group wore her support for only 4 hours a day rather than 8 hours, and she had the largest percentage increase in back extensor strength of this group (78%).

At 16 weeks, decreases in back strength that were more than 5% below the initial measurements were noted in 1 of 11 subjects (9%) who completed the control arm of the study, 2 of 14 (14%) who completed the PTS arm, and 2 of 5 (40%) who completed the thoracolumbar arm.

DISCUSSION

The PTS is a relatively inexpensive, unobtrusive device that we hypothesize promotes improvement in posture and increases in back extensor strength by two mechanisms. First, we suggest that the device produces a force posteriorly below the inferior angles of the scapulae and thereby reduces anterior compressive forces that are commonly exerted on the spine. The force produced by this 0.79-kg (1.75-lb) weight is multiplied by the known severalfold mechanical lever of the spine,[9] and the result is a passive mechanism that may reduce further compression fractures. Second, we believe that the device produces proprioceptive input, which may have a major role in promoting active back extension and thus improved posture as well as increased back extensor strength. Toward this end, the role of back extension exercises in osteoporosis has been well defined.[10,11]

This pilot study provides strong evidence that patient compliance with the PTS is significantly greater than compliance with a conventional thoracolumbar support. Thus, in the absence of a diagnosis that necessitates spinal immobilization (such as an acute compression fracture), this study suggests that the PTS is clearly preferable to a conventional thoracolumbar support. Even for an acute compression fracture, the indications for, clinical usefulness of, and compli-

Table 3.—**Raw Scores for Back Extensor Strength, Grip Strength, and Physical Activity Scale in 15 Patients With Osteopenia or Osteoporosis Who Wore Posture Training Support and Exercised***

	BES (lb)			Grip (R) (lb)			PAS†		
Case	Baseline	8 wk	16 wk	Baseline	8 wk	16 wk	Baseline	8 wk	16 wk
16	40	45	44	45	42	40	5	5	5
17‡	32	47	57	75	70	65	6	6	2
18	41	45	47	55	51	56	5	5	5
19	50	57	65	55	64	59	3	3	3
20	63	47	75	67	63	64	9	9	9
21	44	56	63	55	60	62	5	6	5
22	39	54	50	50	45	41	7	7	7
23	45	43	39	45	46	50	6	6	6
24	25	34	44	55	50	52	4	6	5
25	74	69	69	50	48	47	5	4	5
26	49	63	67	67	67	71	4	7	7
27	42	58	52	60	55	59	6	6	6
28	54	56	53	70	70	77	10	10	10
29	61	85	92	60	73	87	4	4	4
Mean	47	54	58						
Excluded patient									
30§	44	76	54	49	53	52	5	9	8

*BES = back extensor strength; PAS = physical activity scale; R = right hand.
†Range of score is 0-18.
‡Wore support only 4 hours a day, to avoid back pain.
§Had back pain that limited accurate BES measurement at third visit.

ance with a conventional thoracolumbar support are unclear, particularly in light of past studies that have cited noncompliance[5] and known medical contraindications to conventional thoracolumbar supports, such as chronic obstructive pulmonary disease and diaphragmatic hernia, both of which are common.[3] The number of subjects in this study was limited but comparable to the subject sample size in other studies related to compliance with exercise or bracing. The data from the current study are useful for generation of hypotheses, and we hope that they will encourage future studies in this area.

Periodic telephoning of the patients may have resulted in an artificially high compliance rate among study subjects assigned to the PTS and thoracolumbar support. We acknowledge that unintended differential coaching could have unequally increased compliance rates between these groups, although in any event thoracolumbar compliance was clearly unacceptable clinically. Furthermore, the study's fundamental goal of determining the effect of an orthosis on back extensor strength was not compromised.

This study suggests a trend toward increased back extensor strength among patients in the PTS group in comparison with the conventional thoracolumbar group. As noted, this trend was not statistically significant, possibly because of the insufficient power of this baseline study. We acknowledge, however, that an alternative hypothesis is a lack of mechanical effectiveness of the PTS for increasing back strength. Instead, the PTS may function as a proprioceptive reinforcer and as a device to improve patient acceptance of and compliance with back extensor strengthening exercises. Even such a mechanism, however, would be clinically useful because several patients withdrew from the study after randomization as a result of their strong desire for intervention beyond mere instruction in body mechanics and exercise. Furthermore, one patient who wore the PTS for 4 hours a day (pain and discomfort occurred after this amount of time) had a dramatic increase in back extensor strength, and several other patients commented that the PTS was comfortable throughout the day but became burdensome during the last 2 hours of use; thus, future research could explore whether the PTS might be more effective for increasing back extensor strength if used 4 hours a day rather than the conventionally recommended 4 hours twice a day.

CONCLUSION

Patient compliance with the PTS is dramatically better than compliance with use of a conventional thoracolumbar support. A trend may exist (although not statistically significant in this study) toward increased compliance and back extensor strength in patients who use the PTS in addition to performing postural exercises. Our study did not have a large enough sample size to verify such a pattern. Future studies to evaluate the compliance and change in back extensor strength with postural exercises alone in comparison with postural exercises in combination with use of the PTS 4 hours a day and 4 hours twice a day would be helpful.

This preliminary study suggests that future investigations should continue to explore whether long-term use of a conventional thoracolumbar support is advisable in patients with osteoporosis because of potential poor compliance and a potential (although not yet proven) risk of iatrogenically induced weakness. We caution, however, that this pilot study, which reports hypotheses-generating data, requires replication in a larger series in order to determine the clinical and statistical generalizability of these findings to a wider population.

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